

REMARKS

After entry of this preliminary amendment, claims 1-19 and 179-182 are pending in the application with claim 1 in independent form. Claims 20-178 have been canceled.

An Information Disclosure Statement (IDS) and PTO-1449 Form are submitted with this amendment. These documents note all of the previously submitted prior art references supplied in the prior previous copending application Serial No. 10/083,266. The Applicants respectfully request that the Examiner consider the IDS, make it of record, and initial and return a copy of the PTO-1449 Form pursuant to MPEP § 609.

In the parent application, claims 1, 4, 7, and 16-18 stood rejected under 35 U.S.C. §102(b) as being anticipated by Harris (United States Patent No. 4,548,607). The Applicants apply this rejection to the claims now present in the pending application and, once again, respectfully traverse.

The invention as claimed in independent claim 1 requires, among other claim elements, a pump assembly that includes a piston for delivering the medication to the patient and an actuator that is disposed in the base housing. The claimed actuator is not a component of the pump assembly. Irrespective of the piston, the actuator operatively engages both the pump inlet and the pump outlet to retain both the pump inlet and the pump outlet in the open state during sterilization. As such, that the sterilization fluid can penetrate into the medication reservoir, the pump inlet, the pump housing, and the pump outlet to completely sterilize the medication delivery system.

Importantly, the piston and the actuator are separate components in the system of the present invention. To this end, the Applicants have clarified independent claim 1 to make it clear that the system comprises a pump assembly including a piston and that the system also comprises an actuator that is a separate component than the piston and not part of the pump assembly.

Harris does not disclose, teach, or even suggest a medication delivery system that includes such a piston *and* such an actuator.

Instead, the component disclosed in Harris, identified by the Examiner as actuator 44, is simply a part of Harris' pump 20. Harris does not disclose, teach or suggest an actuator that is separate from the pump 20. Said in another manner, the Applicants

recognize that the component 44 of Harris is a similar component compared to the piston 54 of the claimed invention. However, because this is the case, then the component 44 of Harris cannot also be the actuator claimed in independent claim 1 of the present invention.

Furthermore, as set forth in prior arguments, the Applicants again emphasize that the component 44 of Harris does not retain both the pump inlet and the pump outlet in the open state at the same time during sterilization such that a sterilization fluid can penetrate into the entire system to completely sterilize the system. Referring to Figures 5 and 6b where the component 44 is open and in the non-actuated state, although the pump inlet of Harris is in an open state such that medicament can flow into the pump 20, the pump outlet is clearly in a closed state such that medicament cannot flow out of the pump 20. On the other hand, referring to Figure 6a where the component 44 is closed and in the actuated state, although the pump outlet of Harris is in an open state such that medicament can flow out of the pump 20, the pump inlet is clearly in a closed state such that medicament cannot flow into the pump 20.

To this end, the pump inlet and the pump outlet of Harris are never, and physically can never be, both retained in an open state at the same time. As a result, the device of Harris does not disclose, teach, or otherwise suggest the claimed invention, specifically the claimed actuator and, contrary to the Examiner's assertions, the device of Harris cannot perform the function of the claimed invention. That is, all of the components in the device of Harris cannot be completely sterilized at the same time because the component 44 always places one of either the pump inlet or the pump outlet in a closed state and a sterilization fluid, such as EtO gas, would not be able to flow throughout the entire device.

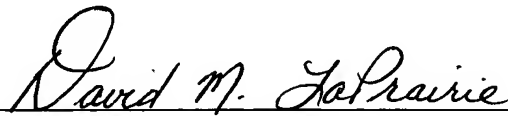
Because, as set forth above, Harris does not anticipate the invention as claimed in independent claim 1, a rejection relying on Harris cannot be maintained and independent claim 1 is patentable. Furthermore, claims 2-19 and 179-182 depend, either directly or indirectly, from claim 1 such that these claims are also patentable.

It is respectfully submitted that the application is now presented in condition for allowance, which allowance is respectfully solicited. Favorable reconsideration of the outstanding office action is hereby requested.

Respectfully submitted,

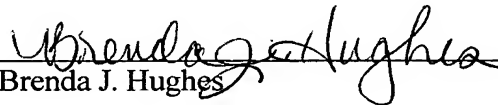
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Date: November 4, 2003


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CERTIFICATE OF EXPRESS MAILING

I hereby certify that the enclosed **Preliminary Amendment, Patent Application, formal drawings, Information Disclosure Statement, PTO-1449 Form, Declaration, Assignment, return post card, and fee** are being deposited with the United States Postal Service as Express Mail, postage prepaid, in an envelope as "Express Mail Post Office to Addressee", Mailing Label No. **EL 993 944 849 US** and addressed to **Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450**, on **November 4, 2003**.


Brenda J. Hughes

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Docket No.: 60,210-193